REMARKS

Claims 1, 3, and 5-18 are pending in the present case. Pursuant to 37 C.F.R.§1.118(a), Applicant respectfully submits that the foregoing arguments do not introduce any new material into the application.

I. Priority

The Examiner notes that that the present application is a CIP of application No. 09/778,294, which is a divisional of Application No. 09/370,654. The Examiner asserts that these applications do not support a combination of beta-glucan and lactoferrin and that the claims drawn to this composition are not granted a priority based upon these applications. Applicant requests clarification that the presently pending claims have priority based upon the provisional application 60/257,013, filed December 20, 2000.

I. Rejections under 35 U.S.C. §102

Claims 1, 3, and 5-15 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by WO97/08960, which corresponds to U.S. Patent No. 6,306,453 (referred to as US '453). The Examiner describes this patent as teaching a composition that contains yeast glucan and lactoferrin, with the glucan specified as beta-glucan. Applicant asserts that the US '453 patent is silent with regard to the length of time that the composition can be administered, and that the administration is "safe" (*e.g.* the administration is substantially without side-effects). Applicant's pending claims require that the composition can be safely administered daily for at least two weeks. According to MPEP 2131, in order to anticipate a claim, the reference must teach each and every element of the claim. Furthermore, the Federal Circuit has found that "the identical invention must be shown in as complete detail as is contained in the claim," *Richardson v. Suzuki Motor Co.*, 868F.2d 1226, 9 USPQ 1913, 1920 (Fed. Cir. 1989). Applicant respectfully

submits that in view of the comments above, U.S. '453 fails to meet these requirements since it does not teach or describe in its claims the safe administration or the length of time for administration of the present composition. Thus, it is respectfully requested that the rejection of claims 1, 3, and 5-15 be withdrawn.

Claims 1, 5, 6, 8, 9, and 12-15 stand rejected under 35 U.S.C. 102(e) as allegedly being anticipated by U.S. Patent No. 6,241,983. The Examiner asserted that this reference teaches a composition containing beta-glucan and lactoferrin (claims 1, 2, and 21). Applicant asserts that the '983 patent claims a composition that contains a mixture of beneficial bacteria and dietary fiber. A dependent claim describes the composition wherein the dietary fiber is β-glucan. Another dependent claim describes the composition as further containing "about 0.0001% to about 0.1000% of lactoferrin and about 0 to about 10% by weight of a member selected from the group consisting of gluconic acid, its nutritionally acceptable salts, and mixtures thereof". ***All of the claims of the '983 patent require the composition to contain a mixture of beneficial bacteria*** along with the other components which in certain claims include various amounts of lactoferrin and β-glucan. Applicant's invention is an entirely different composition and does not require the presence of beneficial bacteria. Furthermore, Applicant's claims recite the safe administration (*e.g.* substantially without side effects) and the length of time for administration of the inventive composition. The '983 patent is silent regarding both the safe administration and the length of time for administration of the composition. In view of these and the reasons described above referencing *Richardson*, it is respectfully requested that the rejection of claims 1, 5, 6, 8, 9, and 12-15 be withdrawn.

Claims 1, 3, and 5-17 stand rejected under 35 U.S.C. 102(e) as allegedly being anticipated by U.S. 2002/0119928. The Examiner asserted that this reference describes a composition containing lactoferrin and beta-glucan, and can also contain colostrum (claims 1, 3-4, and 9). Applicant points out that claims 1, 3-4, and 9 describe a composition that contains at least three components: colostrum, lactoferrin, and beta-glucan. Colostrum is not a flavoring, but an immune system enhancer (a component of breast milk that contains a high concentration of maternal immunoglobulins). Thus, claims 1, 3-4, and 9 are an entirely different composition from Applicant's composition.

Claim 5 of U.S. 2002/0119928 recites "a dietary supplement composition for a mammal, comprising a nutritionally effective amount of β-glucan and lactoferrin." Importantly, Applicant's claims recite the safe administration (*e.g.* substantially without side effects) and the length of time for administration of the inventive composition. The reference U.S. 2002/0119928 is silent with regard to these claim elements, and thus does not teach or anticipate Applicant's invention. Applicant asserts that the present composition is recited to be safely administered for at least two weeks and that these claimed distinctions embrace meaningful and factual differences between the claims at issue and the references cited. In view of these and the reasons described above referencing *Richardson*, it is respectfully requested that the rejection of claims 1, 3, and 5-17 be withdrawn.

II. Rejections under 35 U.S.C. §103

Claims 1, 7, 10, 11, 16, and 17 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over WO 97/08960 (equivalent to US '453). Applicants assert that the safe administration for at least two weeks is a demonstrated, unexpected result, supported by the specification and by data from the declaration filed May 7, 2004, in support of the present

invention. The expected results for the composition comprising *both lactoferrin and β-glucan* have been described as *including the negative effects of swelling, bloating, or aching associated with taking a composition of either beta-glucan or lactoferrin alone, which effects are usually observed within two weeks (or as short as one or several hours).* Applicant maintains that the claimed compositions show unexpected results in that they can be safely administered for an extended period of time (days, weeks, months), during which positive effects are observed without the undesirable negative side-effects encountered by administration of lactoferrin or beta-glucan alone. It is noted that the basis upon which 35 U.S.C. 103 is determined includes the following considerations:

> ***All factual differences which may be properly noted in any portion of claim*** must be included within basis for comparison with prior art if court is to properly evaluate differences between claimed invention and teaching of reference; command of 35 U.S.C. 103 is to compare the invention as a whole with prior art; absent a failure of applicant to comply with section 112, ***every portion of claims must be considered in determining invention as a whole in arriving at decision as to obviousness under section 103.***
> (*in re Duva* (CCPA) 156 USPQ 90) (emphasis added) (referencing the preamble of a claim, but the argument applies to all elements of the claims, as in the present case).

Applicant asserts that the present composition is recited to be safely administered for at least two weeks and that these claimed distinctions embrace meaningful and factual differences between the claims at issue and the references cited.

Additionally, Applicant asserts that the specific amounts of the Applicant's composition components as claimed were not obvious in view of the negative side effects known and described by those of skill in the art in this field when administering either lactoferrin or β-glucan alone. The claimed compositions are not obvious in view of the Applicant's inventive steps identified with regard to the safe administration for extended periods of time of the inventive compositions.

Claims 1, 3, 7, 10, 11, and 16-18 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Patent No. 6,241,983 in view of U.S. Patent No. 5,670,138. The Examiner states that U.S. '983 teaches a composition comprising lactoferrin and beta-glucan but does not specifically teach adding the ingredients in the amounts claimed by applicant. In view of the extensive discussion above, Applicant asserts that the ingredient amounts are not routine, especially in view of such factors relating to the length of time of administration of the composition and the added effect of being safely administered. None of these factors, including the ingredients in the amounts claimed were obvious in view of the negative effects of single administration of lactoferrin or β-glucan.

With regard to the teaching relating to formulating the composition in particular forms (citing U.S. Patent '138, related to ingredients used to formulate orally administered products) including using lemon flavoring, mannitol, sorbitolm and silicon dioxide, it is respectfully submitted that the Examiner has not satisfied the burden of establishing a *prima facie* case of obviousness. None of the references cited by the Examiner provide a motivation or suggestion to combine the '983 and '138 references to support the combination suggested by the Examiner. Absent such motivation or suggestion, it is improper to combine the references in support of an obviousness rejection under 35 U.S.C. §103. The Federal Circuit has consistently held that in order to establish a proper *prima facie* case of obviousness, the PTO must show a motivation, apart from the teaching of the invention, to combine the references. The Federal Circuit reversed an obviousness rejection in a recent case, *In re Rouffet*, where, as in the present case, the Examiner improperly pieced together elements found in the prior art when there was no motivation to do so. The court stated:

> An Examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate

> patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such as approach would be 'an illogical and inappropriate process by which to determine patentability.' To prevent the use of hindsight based on the invention, ***this court requires the Examiner to show a motivation to combine the references*** that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. 47 USPQ2d 1453 (Fed. Cir. 1998) (citations omitted, emphasis added).

See also, *In re Jones*, 21 USPQ2d 1941 (Fed. Cir. 1992), a *prima facie* case of obviousness required evidence, "other than the PTO's speculation (if it can be called evidence)" that one of ordinary skill in the art would have been motivated to make the suggested combination.

Claims 1, 3, 7, 10, 11, and 16-18 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. 2002/0119928 in view of U.S. Patent No. 5,670,138. The Examiner similarly asserts that the '928 reference teaches a lactoferrin and β-glucan composition; but does not specifically teach adding the ingredients in the amounts claimed by applicant. The above arguments relating to the unexpected results of being able to safely administer the inventive compositions for at least two weeks (e.g. having substantially no side effects), are believed to demonstrate unexpected results which logically apply to the claimed ingredients of the compositions (as supported in the inventor's declarations and the specification).

With regard to the teaching relating to formulating the composition in particular forms, including using lemon flavoring, mannitol, sorbitolm and silicon dioxide, it is respectfully submitted that the Examiner has not satisfied the burden of establishing a *prima facie* case of obviousness. As discussed above, it is believed that absent motivation to combine the lactoferrin and β-glucan composition in the amounts or formulations claimed, these rejections should be

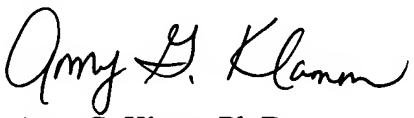
withdrawn. Thus, it is respectfully requested that the rejections of claims 1, 3, 7, 10, 11, and 16-18 be withdrawn in view of the present arguments.

* * * * * * *

In light of the above remarks, reconsideration and withdrawal of the outstanding objections and rejections are respectfully requested. All arguments are made in a good faith effort to advance the prosecution on the merits. The Examiner is encouraged to call the undersigned should any further action be required for allowance.

The Commissioner is authorized to charge the two-month extension fee of $215, to Deposit Account No. 01-2508/13479.0002.CPUS01. Should any additional fees be required for any reason relating to the enclosed materials, the Commissioner is authorized to deduct said fees from Deposit Account No. 01-2508/13479.0002.CPUS01.

Respectfully submitted,



Amy G. Klann, Ph.D.
Reg. No. 48,155
Customer No. 23369
AGENT FOR ASSIGNEE,
LACTOFERRIN PRODUCTS COMPANY

Howrey Simon Arnold & White, LLP
2941 Fairview Park Drive, Box 7
Falls Church, VA 22042
(713) 787-1400 (fax)
713-787-1435 (agent's direct line)

November 1, 2004